Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL QUALITY MEASURES CLEARINGHOUSE

General

Title

Optimizing patient exposure to ionizing radiation: percentage of final reports for CT imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules based at a minimum on nodule size and patient risk factors.

Source(s)

American Board of Medical Specialties (ABMS), American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American College of Radiology (ACR). Optimizing patient exposure to ionizing radiation performance measurement set. Reston (VA): American College of Radiology; 2016 Jan. 51 p. [53 references]

Measure Domain

Primary Measure Domain

Clinical Quality Measures: Process

Secondary Measure Domain

Does not apply to this measure

Brief Abstract

Description

This measure is used to assess the percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size and patient risk factors.

Rationale

Pulmonary nodules are commonly encountered in both primary care and specialty settings (MacMahon et al., 2005; Gould et al., 2007). Pulmonary nodules require appropriate management (to avoid missing early malignancies or conversely subjecting patients to unnecessary follow-up scans (Gould et al., 2007).

At least 99% of all nodules 4 mm or smaller are benign and because such small opacities are common on thin-section computed tomography (CT) scans, follow-up CT is not recommended (Swensen, 2002). Additionally, there is no conclusive evidence that serial CT studies with early intervention for detected cancers can reduce disease-specific mortality, even in high-risk patients. Therefore, follow-up CT for every small indeterminate nodule is not recommended (MacMahon et al., 2005).

The following evidence statements are quoted verbatim from the referenced clinical guidelines and/or other references:

Fleischner Society Recommendations for Follow-up and Management of Nodules Smaller than 8mm Detected Incidentally at Nonscreening CT (MacMahon et al., 2005).
Since the decision to perform follow-up studies relies on size, lesion characteristics (e.g., morphology), and growth rates (typically described as doubling time), an understanding of these features and their relationship to malignancy should dictate further evaluation. In addition, the patient's risk profile, including age and smoking history, needs to be integrated into the diagnostic algorithm.

- Nodule size* less than or equal to 4 mm
  - Low-risk Patient: no follow-up needed†
  - High-risk Patient: follow-up at 12 months; if unchanged, no further follow-up‡
- Nodule size greater than 4 to 6 mm
  - Low-risk Patient: follow-up at CT at 12 months; if unchanged, no further follow-up‡
  - High-risk Patient: initial follow-up CT at 6 to 12 months, then at 18 to 24 months if no change‡
- Nodule size greater than 6 to 8 mm
  - Low-risk Patient: initial follow-up CT at 6 to 12 months, then at 18 to 24 months if no change
  - High-risk Patient: initial follow-up CT at 3 to 6 months, then at 9 to 12 and 24 months if no change
- Nodule size greater than 8 mm
  - Same for Low- or High-risk Patient: follow-up CT at around 3, 9, and 24 months, dynamic contrast enhanced CT, positron emission tomography (PET), and/or biopsy
- Note: Newly detected indeterminate nodule in persons 35 years of age or older.
  - Low-risk Patient: Minimal or absent history of smoking and of other known risk factors.
  - High-risk Patient: History of smoking or of other known risk factors.

*Average of length and width.
†The risk of malignancy in this category (less than 1%) is substantially less than that in a baseline CT scan of an asymptomatic smoker.
‡Nonsolid (ground-glass) or partly solid nodules may require longer follow-up to exclude indolent adenocarcinoma.

These recommendations apply only to adult patients with nodules that are "incidental" in the sense that they are unrelated to known underlying disease. The following examples describe patients for whom the above guidelines would not apply:

- Patients known to have or suspected of having malignant disease. Patients with a cancer that may be a cause of lung metastases should be cared for according to the relevant protocol or specific clinical situation.
- Young patients. Primary lung cancer is rare in persons under 35 years of age (less than 1% of all cases), and the risks from radiation exposure are greater than in the older population. Therefore, unless there is a known primary cancer, multiple follow-up CT studies for small incidentally detected nodules should be avoided in young patients.
- Patients with unexplained fever. In certain clinical settings, such a patient presenting with neutropenic fever, the presence of a nodule may indicate active infection, and short-term imaging follow-up or intervention may be appropriate.

Previous CT scans, chest radiographs, and other pertinent imaging studies should be obtained for comparison whenever possible, as they may serve to demonstrate either stability or interval growth of the nodule in question.

A low-dose, thin-section, unenhanced technique should be used, with limited longitudinal coverage, when follow-up of a lung nodule is the only indication for the CT examination (MacMahon et al., 2005).

Evidence for Rationale

American Board of Medical Specialties (ABMS), American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American College of Radiology (ACR). Optimizing patient exposure to ionizing radiation performance measurement set. Reston (VA): American College of Radiology; 2016 Jan. 51 p. [53 references]

Gould MK, Fletcher J, Iannettoni MD, Lynch WR, Midthun DE, Naidich DP, Ost DE, American College of Chest Physicians. Evaluation of patients with pulmonary nodules: when is it lung cancer?: ACCP evidence-based clinical practice guidelines (2nd edition). Chest. 2007 Sep;132(3 Suppl):108S-30S. [211 references] PubMed

MacMahon H, Austin JH, Gamsu G, Herold CJ, Jett JR, Naidich DP, Patz EF Jr, Swensen SJ, Fleischner Society. Guidelines for management of small pulmonary nodules detected on CT scans: a statement from the Fleischner Society. Radiology. 2005 Nov;237(2):395-400. PubMed

Swensen SJ. CT screening for lung cancer. AJR Am J Roentgenol. 2002 Oct;179:833-6. PubMed

Primary Health Components

Ionizing radiation; computed tomography (CT) imaging studies of the thorax; incidentally detected pulmonary nodules; follow-up

Denominator Description

All final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors

Numerator Description

Final reports with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up computed tomography [CT] imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors (see the related "Numerator Inclusions/Exclusions" field)

Evidence Supporting the Measure

Type of Evidence Supporting the Criterion of Quality for the Measure

A clinical practice guideline or other peer-reviewed synthesis of the clinical research evidence

A formal consensus procedure, involving experts in relevant clinical, methodological, public health and organizational sciences

One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

Additional Information Supporting Need for the Measure

Importance of Topic

The use of medical imaging has resulted in revolutionary advances in the practice of medicine. The increased sophistication and clinical efficacy of imaging have resulted in its considerable growth. Consequently, the evolution of imaging has resulted in a significant increase in the population's cumulative exposure to ionizing radiation and a potential increase in adverse effects including cancer (Amis, Butler, & American College of Radiology [ACR], 2010; Amis et al., 2007). Although experts may not agree on the extent of the risks of cancer from medical imaging, there is uniform agreement that care should be taken to weigh the medical necessity of a given level of radiation exposure against the risks, and that steps should be taken to eliminate avoidable exposure to radiation (Amis et al., 2007; Center for Devices and Radiological Health [CDRH], 2010).

High Impact Topic Area

This topic was chosen for measure development because of the high costs associated with imaging studies and because these medical procedures are a significant source of radiation exposure. The following objective data support the degree of increase in the use of imaging studies and emphasize the importance in taking steps to help eliminate avoidable exposure.

Prevalence and Incidence

- The average per capita exposure to ionizing radiation from imaging exams increased by about 600% from 1980 to 2006 in the United States (U.S.) (Mettler et al., 2009; National Council on Radiation Protection and Measurements [NCRP], 2009).
- The largest contributor to this dramatic increase in population radiation exposure is computed tomography (CT). In 1980 fewer than 3 million CT scans were performed; in 2006, there were about 380 million radiologic procedures (including 67 million CT scans) and 18 million nuclear medicine procedures performed in the U.S. (Mettler et al., 2009).
- The imaging study with the single highest radiation burden, accounting for 22% of cumulative effective dose, is myocardial perfusion imaging (Fazel et al., 2009).
- In 2006, an estimated 19 million head, 10.6 million chest and 21.2 million abdominal and pelvic CT scans were performed accounting for 28%, 15.9%, and 31.7%, respectively, of the total number of CT scans in the U.S. (Mettler et al., 2009).
- Currently, approximately 11% of CT examinations are performed on children, which could account for more than 7 million pediatric CT examinations per year in the U.S. (Mettler et al., 2000; Frush & Applegate, 2004; Linton, Mettler, & NCRP, 2003).
- The prevalence of CT or magnetic resonance imaging (MRI) use during emergency department (ED) visits for injury-related conditions increased from 6% in 1998 to 15% in 2007 (Korley, Pham, & Kirsch, 2010).
- While CT utilization has decreased steadily since 2003 in pediatric facilities across North America (Townsend et al., 2010) the use of CT in children who visit the ED increased from 0.33 to 1.65 from 1995 to 2008 and occurred primarily at non-pediatric focused facilities (Larson et al., 2011).

Costs

- From 2000 through 2006, total Medicare expenditures for physician imaging services increased from $6.7 billion to about $14 billion, an increase of 13% per year on average (U.S. Government Accountability Office [GAO], 2008).
- In 2005 imaging services represented an estimated 14% of 2005 spending included in the sustainable growth rate (SGR) calculation, but represented 27% of the total increase in such spending between 2004 and 2005. The majority of the growth occurred for advanced imaging (GAO, 2008).
- In 2006, advanced imaging, including CT and MRI, accounted for 54% of total Medicare imaging expenditures, up from 43% in 2000. This translates to an increase in Medicare spending on advanced imaging from about $3 billion in 2000 to about $7.6 billion in 2006 (GAO, 2008).

Disparities

There is variation according to age, sex, and health care market in the proportion and mean dose of

patients undergoing medical imaging procedures. One study concluded that the proportion of subjects undergoing at least one imaging procedure was higher in older patients, rising from 49.5% of those who were 18 to 34 years old to 85.9% of those who were 60 to 64 years old. The study also found that women underwent procedures significantly more often than men, with a total of 78.7% of women undergoing at least one procedure during the study period, as compared with 57.9% of men (Fazel et al., 2009).

Opportunity for Improvement
One retrospective cross-sectional study describing radiation dose associated with some of the most common types of diagnostic CT found variable radiation doses. The study found variability in the following exams: 1) routine chest exam without contrast, the CT effective doses ranged from 2 mSv to 24 mSv; 2) routine abdomen-pelvis, no contrast - CT effective dose ranged from 3 mSv to 43 mSv; 3) routine head exam - CT effective dose ranging from 0.3 mSv to 6 mSv (Smith-Bindman et al., 2009).

A central database established for collecting dose indices as a function of patient qualities (i.e., gender, age, size, etc.) and exam type (i.e., lateral lumbar spine, pelvis CT, etc.), would allow the relative range of radiation dose indices to be analyzed and compared against established benchmarks.

Pulmonary nodules have been identified in 8% up to 51% of individuals at the time of baseline low-dose CT screening (Gould et al., 2007; Benjamin et al., 2003). Compared with larger nodules, nodules that measure less than 8 to 10 mm in diameter are much less likely to be malignant and typically defy accurate characterization by imaging tests (Gould et al., 2007).

One study found no cancer in patients in whom the largest noncalcified nodule detected at initial CT was less than 5.0 mm in diameter. Thus there was no advantage in performing short-interval follow-up for nodules smaller than 5 mm in their study, even in high-risk patients (Henschke et al., 2004).

Because of the high frequency with which small pulmonary nodules are detected by CT, the number of resultant follow-up scans is a substantial source of patient anxiety, radiation exposure, and medical cost (Benjamin et al., 2003).

Evidence for Additional Information Supporting Need for the Measure

American Board of Medical Specialties (ABMS), American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American College of Radiology (ACR). Optimizing patient exposure to ionizing radiation performance measurement set. Reston (VA): American College of Radiology; 2016 Jan. 51 p. [53 references]

Amis ES Jr, Butler PF, American College of Radiology. ACR white paper on radiation dose in medicine: three years later. J Am Coll Radiol. 2010 Nov;7(11):865-70. PubMed

Amis ES Jr, Butler PF, Applegate KE, Birnbaum SB, Brateman LF, Hevezi JM, Mettler FA, Morin RL, Pentecost MJ, Smith GG, Strauss KJ, Zeman RK, American College of Radiology. American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol. 2007 May;4(5):272-84. PubMed

Benjamin MS, Drucker EA, McLoud TC, Shepard JA. Small pulmonary nodules: detection at chest CT and outcome. Radiology. 2003 Feb;226(2):489-93. PubMed

Center for Devices and Radiological Health (CDRH). Initiative to reduce unnecessary radiation exposure from medical imaging. Silver Spring (MD): U.S. Food and Drug Administration, Center for Devices and Radiological Health; 2010 Feb. 12 p.

Fazel R, Krumholz HM, Wang Y, Ross JS, Chen J, Ting HH, Shah ND, Nasir K, Einstein AJ, Nallamothu BK. Exposure to low-dose ionizing radiation from medical imaging procedures. N Engl J Med. 2009 Aug 27;361(9):849-57.

Frush DP, Applegate K. Computed tomography and radiation: understanding the issues. J Am Coll Radiol. 2004 Feb;1(2):113-9. PubMed

Gould MK, Fletcher J, Iannettoni MD, Lynch WR, Midthun DE, Naidich DP, Ost DE, American College of Chest Physicians. Evaluation of patients with pulmonary nodules: when is it lung cancer?: ACCP evidence-based clinical practice guidelines (2nd edition). Chest. 2007 Sep;132(3 Suppl):108S-30S. [211 references] PubMed

Henschke CI, Yankelevitz DF, Naidich DP, McCauley DI, McGuinness G, Libby DM, Smith JP, Pasmantier MW, Miettinen OS. CT screening for lung cancer: suspiciousness of nodules according to size on baseline scans. Radiology. 2004 Apr;231(1):164-8. PubMed

Korley FK, Pham JC, Kirsch TD. Use of advanced radiology during visits to US emergency departments for injury-related conditions, 1998-2007. JAMA. 2010 Oct 6;304(13):1465-71. PubMed

Larson DB, Johnson LW, Schnell BM, Goske MJ, Salisbury SR, Forman HP. Rising use of CT in child visits to the emergency department in the United States, 1995-2008. Radiology. 2011 Jun;259(3):793-801. PubMed

Linton OW, Mettler FA, National Council on Radiation Protection and Measurements. National conference on dose reduction in CT, with an emphasis on pediatric patients. AJR Am J Roentgenol. 2003 Aug;181(2):321-9. PubMed

Mettler FA Jr, Wiest PW, Locken JA, Kelsey CA. CT scanning: patterns of use and dose. J Radiol Prot. 2000 Dec;20(4):353-9. PubMed

Mettler FA, Bhargavan M, Faulkner K, Gilley DB, Gray JE, Ibbott GS, Lipoti JA, Mahesh M, McCrohan JL, Stabin MG, Thomadsen BR, Yoshizumi TT. Radiologic and nuclear medicine studies in the United States and worldwide: frequency, radiation dose, and comparison with other radiation sources--1950-2007. Radiology. 2009 Nov;253(2):520-31. PubMed

National Council on Radiation Protection and Measurement (NCRP). Ionizing radiation exposure of the population of the United States. Bethesda (MD): National Council on Radiation Protection and Measurement (NCRP); 2009.

Smith-Bindman R, Lipson J, Marcus R, Kim KP, Mahesh M, Gould R, Berrington de Gonzalez A, Miglioretti DL. Radiation dose associated with common computed tomography examinations and the associated lifetime attributable risk of cancer. Arch Intern Med. 2009 Dec 14;169(22):2078-86.

Townsend BA, Callahan MJ, Zurakowski D, Taylor GA. Has pediatric CT at children's hospitals reached its peak?. AJR Am J Roentgenol. 2010 May;194(5):1194-6. PubMed

U.S. Government Accountability Office (GAO). Medicare Part B imaging services: rapid spending growth and shift to physician offices indicate need for CMS to consider additional management practices. Washington (DC): U.S. Government Accountability Office (GAO); 2008 Jun. 49 p.

Extent of Measure Testing

The measures in this set are being made available without any prior formal testing. However, many of the measures in this set (Utilization of a Standardized Nomenclature for CT Imaging Description, Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies, CT Images Available for Patient Follow-Up and Comparison Purposes, Search for Prior CT Studies through a Secure, Authorized, Media-free, Shared Archive, Appropriateness: Follow-up CT Imaging for

Incidentally Detected Pulmonary Nodules According to Recommended Guidelines and Reporting to a Radiation Dose Index Registry) have been in use in the Centers for Medicare and Medicaid Services (CMS) Physician Quality Reporting System program since 2013 indicating the feasibility of collecting the data elements required for measure calculation.

The American College of Radiology (ACR) recognizes the importance of thorough testing all of its measures and encourages ongoing robust testing of the Optimizing Patient Exposure to Ionizing Radiation measurement set for feasibility and reliability by organizations or individuals positioned to do so. The ACR will welcome the opportunity to promote such testing of these measures and to ensure that any results available from testing are used to refine the measures on an ongoing basis.

Evidence for Extent of Measure Testing

American Board of Medical Specialties (ABMS), American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American College of Radiology (ACR). Optimizing patient exposure to ionizing radiation performance measurement set. Reston (VA): American College of Radiology; 2016 Jan. 51 p. [53 references]

State of Use of the Measure

State of Use

Current routine use

Current Use

not defined yet

Application of the Measure in its Current Use

Measurement Setting

Ambulatory/Office-based Care

Ambulatory Procedure/Imaging Center

Emergency Department

Hospital Inpatient

Hospital Outpatient

Professionals Involved in Delivery of Health Services

not defined yet

Least Aggregated Level of Services Delivery Addressed

Individual Clinicians or Public Health Professionals

Statement of Acceptable Minimum Sample Size

Does not apply to this measure

Target Population Age

Age greater than or equal to 18 years

Target Population Gender

Either male or female

National Strategy for Quality Improvement in Health Care

National Quality Strategy Aim

Better Care

National Quality Strategy Priority

Health and Well-being of Communities
Making Care Safer
Prevention and Treatment of Leading Causes of Mortality

Institute of Medicine (IOM) National Health Care Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Safety

Data Collection for the Measure

Case Finding Period

Unspecified

Denominator Sampling Frame

Patients associated with provider

Denominator (Index) Event or Characteristic

Diagnostic Evaluation

Patient/Individual (Consumer) Characteristic

Denominator Time Window

not defined yet

Denominator Inclusions/Exclusions

Inclusions
All final reports for computed tomography (CT) scan imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors

Exclusions
Unspecified

Exclusions/Exceptions

not defined yet

Numerator Inclusions/Exclusions

Inclusions
Final reports with documented follow-up recommendations* for incidentally detected pulmonary nodules (e.g., follow-up computed tomography [CT] imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors

**Follow-up Recommendations*: No follow-up recommended in the final CT report OR follow-up is recommended within a designated time frame in the final CT report. Recommendations noted in the final CT report should be in accordance with recommended guidelines.

Exclusions
Unspecified

Numerator Search Strategy

Fixed time period or point in time

Data Source

Registry data

Type of Health State

Does not apply to this measure

Instruments Used and/or Associated with the Measure

Unspecified

Computation of the Measure

Measure Specifies Disaggregation

Does not apply to this measure

Scoring

Rate/Proportion

Interpretation of Score

Desired value is a higher score

Allowance for Patient or Population Factors

not defined yet

Standard of Comparison

not defined yet

Identifying Information

Original Title

Measure #3: appropriateness: follow-up computed tomography (CT) imaging for incidentally detected pulmonary nodules according to recommended guidelines.

Measure Collection Name

Optimizing Patient Exposure to Ionizing Radiation Performance Measurement Set

Submitter

American College of Radiology - Medical Specialty Society

Developer

American College of Radiology - Medical Specialty Society

Physician Consortium for Performance ImprovementÂ® - Clinical Specialty Collaboration

Funding Source(s)

Unspecified

Composition of the Group that Developed the Measure

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Financial Disclosures/Other Potential Conflicts of Interest

None of the members of the Patient Optimizing Patient Exposure to Ionizing Radiation Work Group had any disqualifying material interests under the Physician Consortium for Performance Improvement (PCPI) Conflict of Interest Policy.

Measure Initiative(s)

Physician Quality Reporting System

Adaptation

This measure was not adapted from another source.

Date of Most Current Version in NQMC

2016 Jan

Measure Maintenance

This measure set is reviewed and updated every 3 years

Date of Next Anticipated Revision

2017

Measure Status

This is the current release of the measure.

The measure developer reaffirmed the currency of this measure in March 2017.

Measure Availability

Source available from the American College of Radiology (ACR) Web site .

For more information, contact ACR at 1891 Preston White Drive, Reston, VA 20191; Phone: 703-648-8900; E-mail: info@acr.org; Web site: www.acr.org .

NQMC Status

This NQMC summary was completed by ECRI Institute on November 4, 2015. The information was verified by the measure developer on December 29, 2015.

The information was reaffirmed by the measure developer on March 3, 3017.

Copyright Statement

This NQMC summary is based on the original measure, which is subject to the measure developer's copyright restrictions.

Production

Source(s)

American Board of Medical Specialties (ABMS), American Medical Association-convened Physician Consortium for Performance ImprovementÂ® (PCPIÂ®), American College of Radiology (ACR).

Optimizing patient exposure to ionizing radiation performance measurement set. Reston (VA): American College of Radiology; 2016 Jan. 51 p. [53 references]

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